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RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte HANS-URICH PETEREIT, THOMAS BECKERT, MANFRED ASSMUS, WERNER HOESS, WOLFGANG FUCHS, and HARTMUT SCHIKOWSKY

Appeal 2007-4001
Application 09/913,720
Technology Center 1600

Oral Hearing Held: January 22, 2008

Before DONALD E. ADAMS, LORA M. GREEN, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

ON BEHALF OF THE APPELLANTS:

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The above-entitled matter came on for hearing on Tuesday, January 22, 2008, commencing at 9:54 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Janice A. Salas, Notary Public.

THE CLERK: Calendar Number 34, Appeal Number 2007-4001, Mr. Doughty.

JUDGE ADAMS: Is it Mr. Doughty or Mr. Doughty?

MR. DOUGHTY: Doughty.

JUDGE ADAMS: And if you wouldn't mind, could you take a moment and spell your name for the record.

MR. DOUGHTY: Sure. That's D-O-U-G-H-T-Y, Doughty. My first name is Jacob.

JUDGE ADAMS: And we've considered the record and you have 20 minutes, and you can begin when you're ready.

MR. DOUGHTY: Thank you. May it please the Board, my name is Jacob Doughty and I represent the appellants in this matter. Good morning, Your Honors.

Claim 1, the only independent claim subject to appeal right now, is a method claim and it includes four steps. There's melting of the particular monomer mixture, devolatilizing the molten mixture, injecting the mixture into a mold and removing the molded product.

The polymer mixture includes a polymer based on C1 to C4 alkyl esters of acrylic or methacrylic acid and the mixture further includes a release agent in a small amount.

This process is an improvement on the process disclosed in the primary reference Lehmann, which is owned by the same assignee as the present application.

JUDGE LEBOVITZ: So when you say it's an -- maybe you're getting to it and I apologize, but when you say it's an improvement, I just want to establish that it looks like what the examiner is alleging here is that

you've got the same polymer, you've got a release agent, but what's lacking is the devolatilization step.

MR. DOUGHTY: That's right.

JUDGE LEBOVITZ: And the examiner is saying Vetter uses devolatilization, so it would be obvious to have applied that step to Lehmann's polymer mixture.

MR. DOUGHTY: That's correct.

JUDGE LEBOVITZ: Correct?

MR. DOUGHTY: Yep.

JUDGE LEBOVITZ: So that will be the point that you'll be addressing today?

MR. DOUGHTY: Absolutely.

So as we're just discussing, the improvement of the invention claim 1 over Lehmann is devolatilizing the mold mixture, okay; otherwise, the methods are virtually the same, as you point out.

The examiner in the case admits that Lehmann doesn't disclose devolatilizing as provided in claim 1.

The examiner looks to the Vetter reference to remedy this deficiency in Lehmann. Vetter discloses a process like the process of Lehmann and the process of claim 1 in which a polymer mixture is melted. The mixture is injected into a mold and a molded product is removed from the mold.

Vetter, unlike Lehmann, includes a step of devolatilizing the melted polymer mixture; however, the devolatilization step employed in Vetter is used to solve a problem that doesn't exist in Lehmann.

In particular, in Vetter, a volatile liquid treatment agent, like for

-- in most of the examples, it's an ammonia or an amine -- is added to the melted polymer mixture and then must subsequently be driven off, okay?

So in Lehmann, there is no volatile liquid treatment agent that is added to the polymer mixture, and thus, there's no reason to conduct devolatilization to remove a volatile liquid treatment agent.

So according to the modified Lehmann in the way that the examiner proposes is to add a superfluous step. There's nothing in either of the references indicating that such a step would have any value in the method -- in a method such as disclosed in Lehmann.

So obviousness, the concept of obviousness has developed recently, particularly in view of the case, our case, but there still needs to be an apparent reason to combine known elements to obtain the claimed combination.

JUDGE LEBOVITZ: Well, what about this. I mean, Vetter, I think -- number 1, I think Vetter's disclosure is broader. He said to remove any impurities.

MR. DOUGHTY: True.

JUDGE LEBOVITZ: Number 2 -- and you mentioned this several times in the brief, so I wanted to come to this issue.

MR. DOUGHTY: Mm-hmm.

JUDGE LEBOVITZ: He also says you can add water and water will carry off the polymers monomers.

MR. DOUGHTY: Sure.

JUDGE LEBOVITZ: Correct?

And you point and the examiner points to page 11 of the spec.

MR. DOUGHTY: Mm-hmm.

JUDGE LEBOVITZ: The examiner points to page 11 and says, "Appellant has admitted that the copolymer has water in it." If you look at page 11, it says that it -- it's what absorbs water present in the air.

So based on that and Vetter telling you that if you do the devolatilization step and there's water present, it will pull off some of the monomers, wouldn't that make it obvious to apply Vetter's step when you know that the copolymer has -- absorbs water?

And then you know from Vetter that the devolatilization step will not only remove the water, but it will also remove monomer --

MR. DOUGHTY: Okay. First, it's my understanding that there's nothing in the references -- aside from what we might cite in our specification, there's nothing in the references indicating that the particular polymer mixture in Lehmann that there's -- that there's water present or there's some volatile component that needs to be driven off.

JUDGE LEBOVITZ: But what about page 11 of your spec?

MR. DOUGHTY: But that's my specification.

JUDGE LEBOVITZ: But it seems to admit there no boiling constituents are mainly water absorbed from the moisture present in air or derived from the polymer -- this is a commercial form that you're talking about.

MR. DOUGHTY: Right, and it's the discovery that we can improve this commercial form by driving off this liquid. Like, for example, according to my client -- and this is not in the record.

But according to the client, there's no indication that even the commercial literature relating to the particular polymers that are used that this water occurs or that this water occurs through storage.

Like, that's -- basically, that's part and parcel of the discovery that makes the devolatilization step -- the discovery that the devolatilization step is going to improve the result. If that makes sense.

JUDGE ADAMS: So your position would be there's nothing in Lehmann that would suggest that there's monomers present.

MR. DOUGHTY: There's nothing in Lehmann that would suggest that monomers are present. That is not to say that there aren't monomers present, and in fact, that's what we've been trying to resolve.

JUDGE ADAMS: Isn't that what Vetter's also trying to resolve?

MR. DOUGHTY: Well, Vetter -- Vetter in passing mentions that this is possibly an alternative. But Vetter -- clearly the intent of Vetter is to remove these ammonium or amines that are added to the composition which are used to imidize a polymer.

So Vetter -- Vetter is dealing directly with this problem of introducing this extra agent in here, which is causing a chemical reaction, so they're trying to remove reactants from a polymer mixture.

JUDGE ADAMS: Sure. Part of what Vetter teaches is a successful method for reducing the content of residual monomers in the melt provides for the incorporation of a small quantity of water into the melt. During the subsequent devolatilization, the water evaporates and carries off with the monomer vapors.

MR. DOUGHTY: Sure.

JUDGE ADAMS: So Lehmann has this same polymethylmethacrylate as Vetter's talking about, and they're -- one of ordinary skill in the art would say, We melt these polymethylmethacrylates.

There's a likelihood you're going to have monomers there.

Vetter says, Let's go through and clean this stuff up. Not only all these other nasties that are in this preparation, but also let's take care of the monomers.

Not saying they're necessarily there, but there's probably a good likelihood that there are going to be these monomers present in this composition. How do you take care of that? You add a little bit of water and then evaporate it all.

Why isn't that a reasonable combination of references, even under KSR?

MR. DOUGHTY: I would just assert that there's -- well, this is certainly a possibility. I would say that there's nothing in the Lehmann reference in particular. The reference is being modified that indicates that this is a problem that needs to be remedied.

JUDGE ADAMS: Monomers are not problems with this particular composition that need to be addressed?

MR. DOUGHTY: According to the reference -- there's nothing in the reference that indicates that that is the case, okay?

While, in fact, that may be the case -- and in fact, that is the case -- that's not the precise problem that we're solving. But we have discovered that by devolatilizing that you can improve performance.

Now, that's not to say that there aren't monomers present in Lehmann, but there's no recognition that these monomers cause any problem with respect to the product that's being obtained.

JUDGE GREEN: But --

MR. DOUGHTY: But there's no indication -- I'm sorry.

JUDGE GREEN: But we read Lehmann as one of ordinary skill in the art would, right?

MR. DOUGHTY: Sure.

JUDGE GREEN: I think one of ordinary skill in the art with polymer chemistry and especially as used in the pharmaceutical arts would understand that most processes or some impurities are leftover monomers.

MR. DOUGHTY: Sure.

JUDGE GREEN: Very few reactions go to 100 percent. So even though Lehmann does not expressly say there are leftover monomers, I think one of ordinary skill in the art would understand, more likely than not, there are leftover.

MR. DOUGHTY: I agree with that and --

JUDGE GREEN: So if you're using this for a pharmaceutical formulation and a devolatilization -- I'm going to pronounce it wrong -- is just well known in the art for removing impurities. I mean, that's not an unusual step to do --

MR. DOUGHTY: Sure.

JUDGE GREEN: -- in these kinds of preparations.

So why would it have been unobvious to one of ordinary skill in the art, given the general understanding of the art, to go ahead and take out any monomers that may have been left over in Lehmann? Even though Lehmann doesn't expressly say that they're there, the understanding is most reactions don't go to 100 percent.

MR. DOUGHTY: Sure, but even if there are monomers present in a product, that doesn't necessarily indicate that they need to be removed, is what I'm saying. So basically, if Lehmann creates a capsule and

this capsule, for instance -- the end product has some monomer related -- you know, in it.

JUDGE GREEN: So basically, your invention is a slightly more pure product than what was in Lehmann.

MR. DOUGHTY: A slightly --

JUDGE GREEN: I mean, pure impurities. You've taken out the water. You've taken out the leftover monomers by doing the devolatilization step.

MR. DOUGHTY: Sure.

JUDGE GREEN: Because you're saying that your product is just a little -- an improvement over Lehmann.

MR. DOUGHTY: It is.

JUDGE GREEN: So, I mean, there must have been a reason why your inventors decided that this product needed to be improved.

MR. DOUGHTY: Sure.

JUDGE GREEN: Because the Lehmann product, as it stands, is commercially available -- I mean, is commercially a viable product, right?

MR. DOUGHTY: I don't know that.

JUDGE GREEN: But we're assuming --

MR. DOUGHTY: Okay.

JUDGE GREEN: -- that it would probably -- because your argument is, Well, why would you improve upon Lehmann?

MR. DOUGHTY: Right.

JUDGE GREEN: But that -- I mean --

MR. DOUGHTY: Like, I'm not saying -- I guess I'm not saying -- I'm not trying to argue that Lehmann is, you know, asserting that it's

perfect or that there's nothing. I'm just saying that there's nothing affirmative in the reference that would lead one of ordinary skill in the art to make the improvement.

JUDGE GREEN: But what I'm saying is you have to read it in the light of what it would be recognized by the ordinary artisan, and the ordinary artisan would understand that there are monomers and impurities and let's go ahead and take those out with an extra step.

I don't see anything obvious -- I mean, anything unobvious about that given the general knowledge of one of ordinary skill in the art reading the Lehmann reference because one would understand that those monomers are present that there may be other impurities present.

MR. DOUGHTY: Okay. But would one recognize that there is something in the product of Lehmann that requires improvement?

Like, for example, sure, one could look at Lehmann and see that it's theoretically possible to improve the product, but if there's nothing in Lehmann that indicates that there's a problem with the product, like, what would drive someone to make that improvement, whereas --

JUDGE GREEN: But you have that all the time in an obviousness rejection.

You have a reference, usually a patent, that says this is a fantastic product, and then we make the combination, and using your analysis, we would probably never find obviousness because most -- most patents don't come out and say, Well, yeah, this product is great, but these are the problems here.

MR. DOUGHTY: Sure.

JUDGE GREEN: So I don't understand -- I mean, I'm saying

you have to broaden out Lehmann to be understood by the ordinary artisan. Lehmann doesn't have to come in and say, Well, these are the problems with my product, in order to make the obviousness rejection.

JUDGE ADAMS: I think you can also look at it from the perspective that what you're arguing is -- at least what I'm hearing you argue is that, yes, monomers may be present in Lehmann, but Lehmann doesn't say it's necessary to remove them.

MR. DOUGHTY: Sure.

JUDGE ADAMS: But Vetter says you can remove these monomers by doing this devolatilization step, so why would it not be obvious in view of these two references?

Sure, Lehmann says -- you know, we'll interpret Lehmann as saying it's not necessary to do it. We'll interpret Vetter as saying, Well, if you want to do it, here's how you do it, right?

MR. DOUGHTY: Sure.

JUDGE ADAMS: So why isn't that obvious? I mean, if you want to do it, go do it the way Vetter did it, and I think that's pretty much how you did it, right?

MR. DOUGHTY: I guess -- I guess -- I don't know. I guess my understanding of what Vetter is teaching, like, I would say that the overall thrust of Vetter is not towards -- I mean, the overall thrust of Vetter is toward addressing volatile additives to a process.

JUDGE GREEN: But Vetter does recognize that you use this particular step to remove impurities in general.

MR. DOUGHTY: In a process in which a volatile liquid is added subsequent to --

JUDGE GREEN: No. But in general.

MR. DOUGHTY: Sure.

JUDGE GREEN: You use this step to remove impurities. That's how it's understood by the ordinary artisan, right? I mean, this is not a new step that you created.

MR. DOUGHTY: No. It's not.

JUDGE GREEN: It's been routinely used in chemical processes for many, many, many years.

MR. DOUGHTY: Sure.

JUDGE GREEN: So that's what -- you have to read Vetter in view of that knowledge of the ordinary artisan, and what Vetter suggests, you can use it to remove any impurities.

So even though it may be directed to a specific embodiment that Vetter was concerned with, Vetter doesn't say, Well, you can't use it to remove other impurities or you wouldn't use this in any other process.

MR. DOUGHTY: Okay.

JUDGE GREEN: Do you understand?

MR. DOUGHTY: I understand what you're saying, and I guess, without getting into the particulars, I certainly see where -- I see what you're saying, and there's the possibility of making the combination.

And clearly, you know, the elements are out there and I -- I mean, I would just stand on the arguments that I made that one of ordinary skill in the art wouldn't have been led in that position.

JUDGE GREEN: But KSR, I mean, really leads us back to what would have been understood by the ordinary artisan, that we don't have to have a specific statement leaning towards --

MR. DOUGHTY: I agree.

JUDGE GREEN: -- the combination.

MR. DOUGHTY: I agree with that.

JUDGE GREEN: And even obvious to try may be sufficient in -- this actually may even be an obvious to try. It may have been obvious to try to further remove all impurities in the context of the Lehmann in order to obtain a more -- a product that's more predictable as you get it out, especially if you're doing pharmaceutical uses.

MR. DOUGHTY: Yeah. I mean, of course you're going to have to make your own sort of weighing in whether or not it's obvious or not.

And the one thing that I would ask that you also take into consideration is the sort of limited data that's provided in the present specification. It's not ideal.

There's only one example that's straight on point to what we're talking about now, but if you look at example 1 and example 3. Example 1 is an example according to the present invention, and example 3 is the identical example; however, there's no venting going on in extrusion, so there's no additional devolatilization step.

And as a result of adding the devolatilization, example 1 provides superior capsules that are obtained in example 3, so --

JUDGE LEBOVITZ: Can we go slowly through that. The examiner says that the examples are not comparative because the first example, I think, was at 160 and the second example was at 180.

So the examples are not comparative or the showing's not side-by-side because conditions were different. He points to the temperature as

being different, 160 to 180, and also the release agent.

MR. DOUGHTY: Right. I think that that is true in the comparison between example 1 and example 2.

JUDGE LEBOVITZ: Yes.

MR. DOUGHTY: And example 2 is addressing the situation in which there is a different amount of mold release agent.

COURT REPORTER: I'm sorry. A different amount of what?

MR. DOUGHTY: There's a different amount of mold release agent.

JUDGE LEBOVITZ: How do you spell mold?

MR. DOUGHTY: M-O-L-D.

JUDGE LEBOVITZ: Okay. I guess the English spelling is M-O-U-L-D.

MR. DOUGHTY: Yeah, yeah.

JUDGE LEBOVITZ: So --

MR. DOUGHTY: So basically -- go ahead.

JUDGE LEBOVITZ: Example 1 and example 2 are not comparative?

MR. DOUGHTY: Well, example 2 is comparative, but it's comparative in a different regard than the conversation that we've been having here. So example 2 is addressing the different amount of mold release agent, okay?

And there are differences in the processing temperature which may or may not be indicative of whether it's commensurate. It's whether it's a good side-by-side comparison.

The applicants read the review that it was, but I think more

germane to the argument that we're having today is the comparison between example 1 and example 3, which is directly on point to the deficiency of Lehmann that we've been discussing, namely the devolatilization step.

JUDGE LEBOVITZ: And can you explain the difference between 1 and 3?

MR. DOUGHTY: Well, the only difference between 1 and 3 is that there is a devolatilization step in example 1 and there is no devolatilization step in example 3; namely in a particular apparatus, the lower part of the extrusion or the extrusion chamber has vents. This is the devolatilization.

JUDGE LEBOVITZ: The vents are closed.

MR. DOUGHTY: Right. So they close the vents.

JUDGE LEBOVITZ: But that's true, but if we go down the path that Vetter suggests, adding a volatilization step to it --

MR. DOUGHTY: Sure.

JUDGE LEBOVITZ: -- then any advantages would not make the subject matter nonobvious. You have to have unexpected results.

Any -- I think there's case law, Baxter, where it says that if you've got -- a process was suggested by the prior art, any advantages flow with the process. It doesn't flow with the suggested process. It doesn't make it nonobvious.

So you've got to have more than an advantage, an unappreciated advantage. You've got to have unexpected results.

MR. DOUGHTY: And the applicant submits that obtaining this improved quality in the capsule is unexpected. I mean --

JUDGE GREEN: But you said "unexpected," and if you

remove impurities, you'll get a better quality product.

MR. DOUGHTY: I mean, I can't -- there's nothing in the record. I can't speak to that. You know, I'm not --

JUDGE GREEN: But it seems to me that's what you're going to get when you start removing impurities, is you're going to get something that's more predictable because it has a more predictable composition and everything else. You've taken that step --

MR. DOUGHTY: That may or may not be true. I mean, the impurities are impurities in the sense that they're not the desired product that you're ending up with, but as to the effect that it's going to have on the physical structure that you're trying to obtain, I mean, it's --

JUDGE GREEN: Yeah, but it's just hard to say without further -- with just this one paragraph at the end of page 19 that that's unexpected.

MR. DOUGHTY: I understand. I'm just asking that it be considered and given weight with everything else that's in the record.

JUDGE ADAMS: All right. You have a few minutes left. Is there anything else you want to --

MR. DOUGHTY: No. That's it.

(Whereupon, the proceedings at 10:14 a.m. were concluded.)